OFFICE OF SPECIAL MASTERS
Filed: September 28, 2007

CHRISTINE DELRIO, as the legal representative of her infant son, LUCAS DELRIO	)	No. 06-499V
Petitioner,	)	
	)	UNPUBLISHED
v.	)	Motion for Judgment on the Record; No Expert Opinion Offered Relating Breath-Holding Spells to Received Vaccinations
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

Stephanie O'Connor, New York, NY, for petitioner.

Nathaniel McGovern, with whom were Peter D. Keisler, Assistant Attorney General, Timothy P. Garren, Director, Mark W. Rogers, Deputy Director, and Catharine E. Reeves, Assistant Director, United States Department of Justice, Torts Branch, Civil Division, Washington, DC, for respondent.

DECISION[1]

On July 5, 2006, petitioner, Christine Delrio, as the legal representative of her infant son, Lucas Delrio, filed a petition pursuant to the National Vaccine Injury

[1] Vaccine Rule 18(b) states that all of the decisions of the special masters will be made available to the public unless an issued decision contains trade secrets or commercial or financial information that is privileged or confidential, or the decision contains medical or similar information the disclosure of which clearly would constitute an unwarranted invasion of privacy. When a special master files a decision or substantive order with the Clerk of the Court, each party has 14 days within which to identify and move for the redaction of privileged or confidential information before the document's public disclosure.

Compensation Program[2] (the Act or the Program), 42 U.S.C. § 300aa-10 et seq. Petitioner alleges that on July 3, 2003, Lucas received diptheria-tetanus-acellular-pertussis ("DTaP"), inactivated polio virus ("IPV"), hemophilus influenza type B ("Hib"), and pnuemococcal vaccinations. Petitioner also alleges that after receiving these vaccinations, Lucas suffered an "acute encephalopathy, indicated by two separate episodes where he lost consciousness for several seconds, turned blue, and experienced brief shaking activity." Petition (Pet.) at ¶ 6-7. Petitioner asserts that since the onset of his symptoms on July 3, 2003, Lucas has continued to experience "twitching and seizure-like activity on a regular basis . . . ." Id. at ¶ 9.

On October 5, 2006, Ms. Delrio filed on behalf of Lucas: (1) medical records from Pediatric Partners of Glenwood, see Petitioner's Exhibit (P's Ex.) 1; (2) medical records from the Children's Hospital at the University of Colorado, Denver, see P's Ex. 2; (3) medical records from Mountain Valley Developmental Services, see P's Ex. 3; (4) medical records from Sopris Pediatric Therapy, see P's Ex. 4; (5) medical records from Valley View Hospital, see P's Ex. 5; (6) medical records from Colorado Department of Public Health and Environment, see P's Ex. 6; and (7) medical records from Mountain BOCES, see P's Ex. 7.

Respondent filed a Rule 4(c) Report (R's Rept.) on February 8, 2007. In the Rule 4(c) Report, respondent asserted that petitioner was not entitled to Program compensation under the terms of the Vaccine Act. R's Rept. at 2, 14. Specifically, respondent stated that petitioner has yet to offer "a medical or scientific theory causally connecting any vaccine that Lucas received to his breath-holding spells." Id. at 13. Because petitioner has failed to identify a logical sequence of cause and effect between the vaccinations Lucas received and his breath-holding spells, respondent argued that petitioner had not met her burden under the Act, and was not entitled to compensation.

Petitioner did not file an expert opinion. Rather, on June 19, 2007, petitioner simultaneously filed a Status Report (P's SR) and a Motion for Judgment on the Record (P's Mot.) indicating that she "was unable to submit an expert report in support of causation at this juncture . . . ." P's SR at 1.

Petitioner's motion for judgment on the record is now ripe for decision.

I. DISCUSSION

[2] Hereinafter, for ease of reference, all "section" references to the Vaccine Injury Compensation Act will be to the pertinent subdivision of 42 U.S.C. § 300aa (2006 ed.).

A. The Factual Record

Petitioner's son, Lucas, was born on February 2, 2003. P's Ex. 1 at 144. His Apgar scores were eight at one minute and nine at five minutes. Id. The day after his birth, on February 3, 2003, Lucas received his first hepatitis B vaccination. The same day, Ms. Delrio and Lucas were discharged from the hospital with no complications. Id.

Dr. Ellen Brooks was Lucas's pediatrician. During his two-month well-baby examination on April 2, 2003, Lucas received his first dose of DTaP,[3] inactivated polio virus ("IPV"),[4] pneumococcal conjugate,[5] as well as a combined Hib/Hep B (hemophilus influenzae type b/hepatitis B)[6] vaccine. Id. at 1, 87.

Lucas's next exam occurred on July 3, 2003, at age five months. P's Ex. 1 at 78-80. Ms. Delrio expressed concern that Lucas appeared to be "stiff" and that he arched his back frequently, especially when he was being held. Id. at 78. The medical records do not specify the duration of these symptoms, but the symptoms were noted to be getting worse over time. Id. The physical exam was remarkable for truncal and lower extremity hypertonicity. Id. Developmentally, Lucas was normal. Id. at 79. Dr. Brooks discussed the possibility of referring Lucas to a pediatric neurologist or initiating physical and occupational therapy. Id. Lucas received his second DTaP, IPV, Hib, and pneumococcal vaccinations. Id. at 1,79.

Later in the afternoon of July 3, 2003, Ms. Delrio called Dr. Brooks's office to report that Lucas would not eat after his nap, and was vomiting and fussy. Id. at 84. A nurse indicated that Lucas "may be fussy/uncomfortable D/T [due to] immunizations; vomiting may be just a viral episode . . ." Id. The nurse's notes indicate that she

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[3] The DTaP vaccine is "a combination of diphtheria toxoid, tetanus toxoid, and pertussis vaccine; administered intramuscularly for simultaneous immunization against diphtheria, tetanus, and pertussis." Dorland's Illustrated Medical Dictionary 1998 (30th ed. 2003).

[4] The IPV vaccine is "a suspension of formalin-inactivated poliovirus . . . administered intramuscularly or subcutaneously for immunization against poliomyelitis." Dorland's Illustrated Medical Dictionary, supra note 1, at 2000.

[5] The pneumococcal conjugate vaccine protects against infection by the Streptococcus pneumoniae bacteria. Dorland's Illustrated Medical Dictionary 1505, 1999 (30th ed. 2003).

[6] The combination Haemophilus b/hepatitis B vaccine protects against infection by the Haemophilis influenzae type b bacteria and the hepatitis B virus. Dorland's Illustrated Medical Dictionary, supra note 1, at 1999.

instructed Ms. Delrio to call if Lucas's temperature went above 104, or if Lucas showed symptoms of dehydration. Id. The nurse recommended Tylenol for comfort. Id. Dr. Brooks agreed with this assessment. Id.

On July 7, 2003, four days after Lucas had received his second series of vaccinations, Ms. Delrio called Dr. Brooks and reported that Lucas had "passed out" twice over the previous three days. P's Ex. 1 at 77. The first episode had occurred on Friday, July 4, 2003, one day after the vaccinations. Lucas's father was holding Lucas when Lucas suddenly stopped crying. Id. at 76-77. Lucas reportedly "turned blue" and "became limp" for a several seconds, but recovered in the amount of time that it took his mother to cross the room. Id. at 76. The history taken by Dr. Brooks indicated that Lucas was "essentially normal immediately after [the] event." Id. A similar episode occurred two days later. Id. Dr. Brooks concluded that the episodes represented breath-holding spells and were "unlikely to be seizures or related to recent vaccines." Id. at 77. Lucas's older brother was noted to have experienced similar breath-holding spells as a child. Id.

Lucas was evaluated in Dr. Brooks's office on July 8, 2003. P's Ex. 1 at 76. The exam revealed a tendency for Lucas to arch his back when held. Id. There was slightly increased tone in his lower extremities, noted to be resolving. Id. The exam was otherwise unremarkable. Id. The diagnosis was "classic" breath-holding spells. Id. The pediatrician wrote, "Not c[onsistent]/w[ith] cardiac or pulmonary etiology. Not c[onsistent]/w[ith] seizure. Very brief [and] now looks perfectly well. . . doubt related to vaccine." Id. Nonetheless, Dr. Brooks completed a Vaccine Adverse Event Reporting System ("VAERS")[7] report. Id. at 75.

Lucas's next pediatric visit was on September 25, 2003. Dr. Brooks observed that Lucas continued to have hypertonia in his lower extremities. P's Ex. 1 at 73. On examination, his legs were "stiff" and the right leg turned inward. Id. He was receiving

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[7] VAERS is

> a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). VAERS collects and analyzes information from reports of adverse events following immunization. . . . By monitoring such events, VAERS helps to identify any important new safety concerns and thereby assists in ensuring that the benefits of vaccines continue to be far greater than the risks.

Frequently Asked Questions About VAERS, at http://vaers.hhs.gov/vaers.htm (last visited September 26, 2007). Any person can file a report with VAERS. Id.

physical therapy. Id. Reports of "twitching" gave rise to concern about possible seizure activity, although the episodes were reported to be very brief and diminishing in frequency. Id. During this office visit, Lucas received his third DTaP, IPV, Hib, and pneumococcal vaccinations. Id. at 1, 73. Dr. Brooks discussed Lucas's case with a pediatric neurologist, who recommended performing an electroencephalogram if the "unusual/seizure-like behaviors persist[ed]." Id. at 72.

On December 8, 2003, Lucas was seen for influenza. Id. at 71. He was treated symptomatically.

On January 26, 2004, Lucas's parents rushed him to the emergency room because Lucas had another breath-holding spell, which was provoked by his brother taking away some lip balm from him while they were driving in the car. P's Ex 1 at 62. Lucas "started screaming and became very upset. He then exhaled and held his breath." Id. His parents rushed him to the emergency room because he lost consciousness and this was followed by "some brief shaking activity." Id. At the emergency room, Lucas was given "blow-by-oxygen and then he came around to normal." Id. The next day, January 27, 2004, Dr. David Brooks, another pediatrician, evaluated Lucas. P's Ex. 1 at 62-63. The impression was "[c]omplicated pallid breath-holding spell." Id. at 63. Because Lucas's episodes were provoked by emotional distress, Dr. Brooks reasoned that they most likely represented breath-holding spells rather than seizure activity. Id. at 63. Dr. Brooks's notes also reflect, in the family history portion of the record, that Lucas's family history was "[s]ignificant in that his brother had significant breath-holding spells." Id. at 62. Dr. Brooks consulted a pediatric neurologist who agreed with the diagnosis of breath-holding spells and recommended against performing an EEG. Id. at 63.

On February 12, 2004, Dr. Ellen Brooks examined Lucas again and noted that he had an asymmetric smile and that his left leg still turned inwards. P's Ex. 1 at 55. During the preceding two weeks, Lucas had experienced four breath-holding spells accompanied by seizure-like activity. Id. He was suspected to have speech delay, global developmental delay, and possibly cerebral palsy. Id. at 53, 55, 120.

An EEG performed on April 15, 2004, was normal. P's Ex. 5 at 1-2. On June 3, 2004, at sixteen months of age, Lucas was still having two or three breath-holding spells each day, and on average one seizure-like episode per week. P's Ex. 1 at 28. He was hypertonic on the left side and could not walk unassisted. Id. For the first time, significant delays were evident on his Denver Developmental Screening Test. Id. at 2.

On June 8, 2004, Dr. Brooks filed a supplemental VAERS form. P's Ex. 1 at 23-26. Lucas's medical history was summarized as follows:

> On 4/2/03 at 2 mo Lucas received DTaP, comvax, Prevnar, and IPV. He developed unconolable [sic] crying and vomiting later that day. Constipation ensued on 4/15/03. At next W[ell]C[hild]C[heckup] on 7/3/03 mother reported arching/stiff posture esp. of Lower extremities [LEs] which was confirmed on physical. He received DTaP, IPV, Hib, and Prevnar. Mother called on 7/7/03 reporting 2 episodes of 'passing out' since second set of shots. On exam on 7/8/03 confirmed to be c/w classic breath holding spells. These had never occurred prior to this time. VAERS report filed. Lucas seen for 7 mo WCC on 9/25/03 noted by mom to have had some "head twitching", was still having hypertonicity of LE's, and developmental delay. Receiving P[hysical]T[herapy]. Received DTaP, Prevnar, Hepatitis B. Subsequently developed complicated breath holding spells with seizure activity on 1/26/04. Went to ER. No prior seizure activity with breath holding noted and seizure activity only occurs with some of the breath holding spells. Longest seizure with breath holding has been 11 min. per mother. EEG 4/15/04 normal. Lucas remains hypertonic especially on the left and is developmentally delayed but making progress with therapy. No regression ever noted in development.

Id. at 24-25.

On June 26, 2004, Dr. Michael Schaffer, a cardiologist, examined Lucas. P's Ex. 1 at 108. Lucas had a normal electrocardiogram, and the exam revealed no cardiac or neurologic abnormalities. Id. Dr. Schaffer's impression was that "Lucas is having quite typical breath-holding spells." Id. On September 15, 2004, Lucas had a "normal brain MRI. No seizure focus demonstrated." P's Ex. 2 at 6.

On December 15, 2005, two months shy of Lucas's third birthday, Dr. Leston B. Nay, a pediatric neurologist, examined Lucas. See P's Ex. 6. Dr. Nay noted that Lucas's mother reported that Lucas's breath-holding episodes "have continued up to six times per day, but invariably at least once a day, characterized by the development, after anger, frustration, or pain, of crying, then 'tonic-clonic seizures,' sometimes with urination and once with defecation, lasting perhaps 45-60 seconds (by the clock), and followed by a variable period of tiredness before assuming regular activity." Id. at 1.

On examination by Dr. Nay, Lucas was alert and cooperative. P's Ex. 6 at 2. His pupils were equal and reactive to light. Id. His facial movements were symmetrical. Id. Gait and balance were normal. Id. Dr. Nay did not detect any abnormalities in tone or reflexes. Id. Lucas's language development was thought to be appropriate for his age. Id. The impression was "recurring breathholding spells versus epileptiform disorder." Id. Dr. Nay indicated that "the evidence is much better for recurring breath-holding spells,"

but requested a video EEG to ensure that no epileptiform activity was occurring during the episodes. Id. The doctor remarked that Lucas's neurologic exam was normal, and that it would "certainly [be] an unexpected finding if true epileptiform events [were] occurring as frequently as six times a day." Id. at 3.

Lucas was admitted to Children's Hospital of Denver between January 26 and January 28, 2006, for a video EEG. P's Ex. 2 at 21-22. On admission, Lucas was having up to six breath-holding episodes per day. Id. at 21. Ms. Delrio reported that Lucas's most recent generalized tonic-clonic episode had occurred in September 2005 and resulted in loss of bowel and bladder function. Id. His developmental history was notable for global developmental delay. Id. However, the admitting physician noted that Lucas was able to run and jump without any gait abnormality. Id. His speech skills trailed his chronological age by approximately nine months. Id. His fine motor skills were age-appropriate. Id. The video EEG captured one episode of crying followed by cyanosis and tonic posturing. Id. at 93. The EEG was interpreted to be normal (no epileptiform activity) with generalized slowing during the breath-holding episode due to hypoxemia. Id. at 94. The neurologist interpreting the results concluded that "[t]he lack of epileptiform activity supports the diagnosis of cyanotic syncopal spells rather than epilepsy." Id.

B. Legal Standard and Analysis

The Vaccine Act permits a petitioner to prove entitlement to compensation by showing that either: (1) the vaccinee suffered an injury listed on the Vaccine Injury Table within the prescribed time period, commonly referred to as a "Table" case, see § 300aa-14(a); or (2) the vaccinee suffered an injury that is not listed on the Vaccine Injury Table or did not occur within the prescribed time period, but is caused in fact by the received vaccination, commonly referred to as an "off-Table" case, see § 300aa-11(c)(1)(C)(ii)(I). By either method, petitioner bears the burden of proving her claim by a preponderance of the evidence. § 300aa-13(a)(1).

1. No Table Injury Occurred

In a "Table" case, a petitioner benefits from a presumption of causation. See § 300aa-14(a); 42 C.F.R. § 100.3(a). Petitioner in this case alleges that Lucas suffered from an "acute encephalopathy" following his July 3, 2003 vaccinations. See Petition ¶ 7. To prove that Lucas suffered an on-Table encephalopathy, petitioner must establish the occurrence of an "acute encephalopathy" within seventy-two hours of vaccine administration, followed by a "chronic encephalopathy" lasting at least six months. 42 C.F.R.§ 100.3(b)(2). The Qualifications and Aids to Interpretation ("QAI") set forth in

the Vaccine Regulations, provides guidance regarding what symptoms might indicate the occurrence of an "acute encephalopathy." 42 C. F. R. § 100.3.

The QAI provides that for children less than 18 months of age, an "acute encephalopathy" is evidenced by a "significantly decreased level of consciousness" persisting for 24 hours or more, which cannot be attributed to a postictal state (seizure) or medication. 42 C.F.R. § 100.3(b)(2)(i)(A). A finding of a "significantly decreased level of consciousness," according to the QAI, requires at least one of the following clinical signs lasting 24 hours or longer:

> (1) decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
>
> (2) decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
>
> (3) inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

42 C.F.R. §100.3(b)(2)(i)(D).

The medical records establish that Lucas did not experience an acute encephalopathy following his July 3, 2003 vaccinations. Although Lucas had a breath-holding spell on July 4, 2003, and again on July 6, 2003, it appears from his medical records that these spells involved only transient lapses in consciousness. The contemporaneous records document that the first episode lasted several seconds and that Lucas was "essentially normal immediately after [the] event." P's Ex. 1 at 76. The second occurrence was similar to the first episode but less pronounced, lasting just a "few seconds." Id. at 76, 77. When evaluated by his pediatrician on July 8, 2003, Lucas exhibited no signs of diminished mental status. Id. at 76. In fact, Dr. Brooks recorded that Lucas was "now fine" and "looks perfectly well." Id. Lucas's exam did not reveal any symptoms of an encephalopathy, and none of the medical records implicate that condition in his clinical course. Instead, Lucas's symptoms were "classic" for breath-holding spells, the condition that was immediately diagnosed by his pediatrician. This diagnosis was subsequently confirmed by at least two pediatric neurologists. P's Ex. 6 at 2-3; P's Ex. 2 at 94.

Because the record does not support a finding that Lucas suffered an encephalopathy, petitioner is not entitled to a presumption of vaccine causation and must instead proceed on a theory of causation-in-fact.

2. No Off-Table Injury Occurred

To establish entitlement to Program compensation without the presumption of causation, petitioner must prove, by a preponderance of the evidence, that the vaccinations that Lucas received caused his injury. Petitioner satisfies this burden of proof "by providing: (1) a medical theory causally connecting [Lucas's] vaccination and [his] injury; (2) a logical sequence of cause and effect showing that [Lucas's] vaccination was the reason for [his] injury; and (3) a showing of a proximate temporal relationship between [Lucas's] vaccination and [his] injury." Althen v. Sec'y of Dept. of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). The logical sequence of cause and effect proffered by petitioner must be supported by a reputable scientific or medical explanation. Grant v. Sec'y Dept. of Health and Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992); Knudsen v. Sec'y of Dept. of Health and Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994) (stating that a causation theory before a special master must be supported by a "sound and reliable" medical or scientific explanation). The Vaccine Rules reiterate this requirement, instructing the special master to ensure that evidence be "relevant and reliable." RCFC App. B, Vaccine Rule 8(c).

In this case, petitioners have failed to supply any evidence of a causal connection between Lucas's vaccinations and his breath-holding spells. Lucas's medical records reflect only a temporal relationship between his vaccinations and the onset of his breath-holding spells. Dr. Brooks, Lucas's pediatrician, who filed a VAERS report and a supplemental VAERS report, noted in Lucas's records that she "doubt[ed]" that his episodic shaking and loss of consciousness following his breath-holding spells was related to his vaccinations. Petitioner has not offered an expert opinion providing a medical theory causally connecting Lucas's vaccination to his breath-holding spells. Without an opinion of causation from either a treating physician or an expert, petitioner has moved for judgment on Lucas's medical records, stating that she "is unable to meet her burden on causation." P's MJR at 1. Petitioner concedes that "an expert cannot be found to render a favorable opinion concerning causation at this time." Id.

The Vaccine Act prohibits a special master from making a finding of entitlement to compensation based on the claims of a petitioner alone, without substantiation by medical records or by a medical opinion. See § 300aa-13(a)(1). In this case, petitioner's claim is not substantiated by either the filed medical records or an offered medical opinion. Under the Vaccine Act, petitioner's claim must fail.

II. CONCLUSION

The medical records in this case do not establish a causal connection between

Lucas's vaccinations and his breath-holding spells. Petitioner has offered no medical opinion causally connecting Lucas's vaccinations and his breath-holding spells. Because petitioner has failed to establish entitlement to compensation under the Vaccine Act, petitioner's claim is **DISMISSED**. The Clerk of the Court shall **ENTER JUDGMENT** accordingly.[8]

IT IS SO ORDERED.

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Patricia E. Campbell-Smith
Special Master

[8] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of notice renouncing the right to seek review.